

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THE WAVE 1 CASES IDENTIFIED IN EXHIBIT A TO ETHICON’S MOTION	

**PLAINTIFFS’ RESPONSE TO DEFENDANT’S MOTION TO EXCLUDE THE
TESTIMONY DR. GUELCHER, PH.D.**

Defendant’s Motion to Exclude the Testimony of Dr. Guelcher, Ph.D., (“the Motion” or “Defendant’s Motion”), rehashes the same failed arguments that Ethicon made before the *Huskey* trial.¹ Ethicon goes to great lengths to make it appear as though there is nothing to support Dr. Guelcher’s opinions—urging the Court to accept that the decades-old formula for Prolene is uniquely special. The arguments in the Ethicon’s most recent Motion have been litigated before and nothing has changed—indeed, the more that time passes, the more support Dr. Guelcher has in the peer reviewed literature for his opinions. They are beyond reproach.

Dr. Guelcher is a Chemical Engineer with over twenty (20) years of experience in biomaterials and chemical engineering. The opinions he offers in these Wave 1 cases are the same as the opinions that the Court determined to be relevant and reliable in *Huskey v. Ethicon*.² And Dr. Guelcher still bases his opinions on: the principles of biomaterial science; the Prolene oxidation studies Ethicon performed internally; over two decades of experience in biomaterials

¹ *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 709-710 (S.D. W. Va. 2014).

² *Id.* at 701.

and implant design; and dozens of peer-reviewed publications—including ones that he, himself, has published.³

Ethicon's arguments to exclude Dr. Guelcher are stale and encumbered. The Motion itself spends more than four pages describing what it calls a "FACTUAL STATEMENT."⁴ Yet these supposed facts are instead a series of twists and turns through time using only out-of-context testimony. At its core, Ethicon is just rehashing the same issue that it has argued since Dr. Guelcher was first designated as an expert in this litigation; namely: that without peer-reviewed literature describing the *in vivo* oxidation of Prolene, *specifically*, Dr. Guelcher's opinions must be excluded. This argument is made despite the fact that Dr. Guelcher's reliance materials include published, peer-reviewed literature from 1998 that describes finding oxidation on explanted Prolene sutures.⁵ This same argument was rejected in *Huskey*, was raised again in *Mullens*, and is now before the Court in these Wave 1 cases. Ethicon's argument has not been, nor should it ever be, accepted by this Court or any other.

This Court has routinely held that experts with qualifications similar to Dr. Guelcher's are permitted to offer general causation opinions based upon: (1) the peer-reviewed scientific literature; (2) their education and experience; and (3) their review of SEM images and other relevant evidence.⁶ There is no reason why the Court should go against its previous rulings (and the other progeny of *Daubert*) in the present case. Ethicon's Motion fails on all counts and the Plaintiffs respectfully ask that it be denied in full.

³ See Ex. A, Guelcher Report and Ex. B, Guelcher Reliance Materials.

⁴ Def's Brief at 2-7

⁵ Ex. C, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, *ASAIO Journal*, 44 (1998) 199-206

⁶ *Huskey*, 29 F. Supp. 3d 691; *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195 2013 U.S. Dist. LEXIS 149976, (S.D. W.V. Oct. 18, 2013); *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047 (S.D. W. Va. May 6, 2015).

STANDARD OF LAW

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by “knowledge, skill, experience, training or education.” Fed. R. Evid. 702. The witness’s testimony also must represent “scientific knowledge,” meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995).

The court’s focus in a *Daubert* inquiry should be solely on the expert’s “principles and methodology, not on the conclusions that they generate.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Notably, “the Supreme Court itself viewed *Daubert* as a *liberalization*, not a tightening, of the rules controlling admission of expert testimony.” *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996) (emphasis added). Further, “exclusion is the least favored means of rendering questionable scientific evidence ineffective.” *Id.*

ARGUMENT

I. DR. GUELCHER’S OPINIONS ARE RELEVANT AND RELIABLE

Ethicon’s arguments to exclude Dr. Guelcher’s opinions and testimony are well-worn. This Court has already determined that Dr. Guelcher’s opinions are relevant to the ultimate question of liability that the jury will be asked to decide in these cases, and that his opinions are reliably based in the scientific method and otherwise sound under FRE 702 and *Daubert*.⁷ And Dr. Guelcher’s opinions on how the foreign body response oxidizes and degrades Ethicon’s Prolene-polypropylene-based mesh inside the body are central to the jury understanding the defective nature of the products at issue.

⁷ *Huskey*, 29 F. Supp. 3d at 701.

What is more, the reliability of his expert opinions cannot be seriously challenged. They are supported by peer-reviewed literature describing the foreign body response to biomaterials, including what happens to polypropylene mesh inside the body.⁸ Furthermore, Ethicon researchers performed several internal oxidation studies on their Prolene-polypropylene-blend long before the SUI and POP products at issue were ever implanted into women.⁹ Those internal studies led Ethicon's researchers to the same conclusion that the scientific literature has held for decades: that Ethicon's Prolene oxidizes after implantation and that its properties degrade over time. There is no conflict between the opinions Dr. Guelcher offers here and what the scientific literature—or even Ethicon's own research—has to say about polypropylene blends, including Prolene.¹⁰ His opinions are reliable.

A. Dr. Guelcher is not relying on an unfinished study that he designed with Dr. Russell Dunn.

Much of Ethicon's Motion to exclude Dr. Guelcher's testimony focuses on some testing he performed on Prolene mesh with his colleague Dr. Dunn. The Motion argues that this testing is central to Dr. Guelcher's opinions, and since he is not relying on it, he has no evidence that Prolene oxidizes and degrades inside the body.¹¹ This is simply not true. This testing was never central to his opinions in these cases. And, as the Court has already acknowledged, his opinions are sufficiently, and independently, supported by the relevant scientific literature. Indeed, as this Court rightly decided in *Huskey*, testing and/or peer-reviewed literature describing the oxidation and degradation of Prolene, *specifically*, was not necessary when looking at the totality of the support that Dr. Guelcher has for his opinions. Moreover, Dr. Guelcher's opinions are

⁸ Ex. A. Dr. Guelcher's Expert Report, generally.

⁹ Ex A, Dr. Guelcher's Expert Report at 9-10.

¹⁰ See Ex D, ETH.MESH.05453719, 7 year internal oxidation study; see also Ex B, Celine Mary, , Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206

¹¹ Def's Brief at 7-8

unchanged from the ones allowed by this Court in the *Huskey* case and the Motion offers nothing new that could exclude Dr. Guelcher's opinions.

Ethicon tries to support its argument with the critiques of this study, and of Dr. Guelcher's opinions, offered by its own experts, Drs. Thames and MacLean. But the opinions of these defense experts are nonspecific and uninformed; moreover, under the principles of Rule 702 and *Daubert*, conflicting expert testimony, alone, cannot support excluding Dr. Guelcher's testimony because it is not the Court's job to determine which expert is correct, but instead it is to act in as a gate-keeper preventing unreliable and unsupported opinions from being heard by a jury.¹² Dr. Guelcher formed his opinions using the published, peer-reviewed literature, his education, over 20 years' experience in the biomaterials industry, as well as his review of Ethicon's internal documents and studies that conclude, among other things, that Prolene oxidizes and degrades inside the body. His opinions are just as reliable now as they were for the *Huskey* case.¹³

B. Ethicon's insistence that Prolene is special has been previously rejected.

Like it did in *Huskey* and *Mullens*, Ethicon once again takes several unsupported positions regarding "the important chemical differences between generic polypropylene and PROLENE."¹⁴ Indeed, Ethicon simply retreads old ground by arguing that Dr. Guelcher relies on studies that: (1) do not assess Prolene; (2) cannot confirm that Prolene oxidizes inside the body; and (3) do not test or assess the ability of Prolene's antioxidants to slow the degradation

¹²See *In re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-MD-2244-K 2104 U.S. Dist. LEXIS 97798, at *45 (N.D. Tex. July 18, 2014); see also *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

¹³ *Huskey*, 29 F. Supp. 3d at 701.

¹⁴ *Id.* at 703.

process.¹⁵ This Court has previously rejected these arguments; noting them to be “wholly conceived by lawyers, [and] unfounded in science.”¹⁶ Nothing is new here.

1. There is still no basis to exclude Dr. Guelcher’s opinions.

There is still no scientific support for the arguments in Ethicon’s Motion. As Dr. Guelcher’s report describes, and as he testified at the *Huskey* trial, the antioxidant package in Prolene does not take a woman’s anatomy or the foreign body response into account:

So, as I mentioned before, because of the susceptibility of reactivity of polypropylene with oxygen, we have to add antioxidants. And these are typically packaged as primary and secondary antioxidants, and this technology, again, was worked out largely in the 1960’s...

So the purpose of the antioxidant is to protect against processing at thermal -- sorry -- processing at higher temperatures, [and] long-term exposure to atmospheric oxygen that we breathe. Its purpose is not to protect against reactive oxygen in vivo. It’s not possible because the reactive oxygen, foreign-body reaction, wasn’t discovered until 1990.

So these antioxidant packages, when they were created, they simply didn’t know about the foreign-body reaction [at that time], so this wasn’t taken into account when they were designed.¹⁷

Ethicon’s insistence on the need for literature that specifically addresses the degradation or depletion of the antioxidants found in Prolene is completely erroneous. While Prolene may have been novel in the 1960’s, the blend has not changed since that time, and it was not designed to withstand the foreign body response or its use in this application.

Dr. Guelcher’s opinions are supported by the peer-reviewed literature, his experience and education, as well as the internal studies conducted by Ethicon on the degradation of Prolene and the depletion of its antioxidants while inside the body. His opinions are fully supported and should not be excluded.

¹⁵ Def’s Brief at 7-10.

¹⁶ *Huskey*, 29 F. Supp. 3d at 703.

¹⁷ Ex. E, *Huskey* trial trans., 8/25/2014 at 115:19-25; 117:7-17.

2. Dr. Guelcher properly relies on Ethicon's internal studies, conclusions, and analysis of explanted Prolene sutures, and the FDA's classification of those sutures is irrelevant.

Likewise, Ethicon is simply mistaken when it argues that the company's internal documents, studies, and conclusions on Prolene's oxidation and degradation do not support Dr. Guelcher's opinions. Dr. Guelcher has reviewed all of the data, images, methods, and conclusions from all of the internal studies that were produced in this litigation.¹⁸ Indeed, Ethicon cannot contest that its own internal studies concluded that Prolene oxidizes and degrades inside the body. Instead, Ethicon argues that those studies lack conclusive proof that Prolene degrades inside the body, and that confirmation of degradation should have been done through molecular weight analysis, tensile testing, and other means.¹⁹ This argument fails completely.

Notwithstanding whether or not Ethicon's internal studies went far enough in how they assessed Prolene's oxidation and degradation, the researchers involved concluded that it oxidizes and degrades inside the body and the studies back those conclusions.²⁰ Dr. Guelcher's opinions are based on those conclusions, the SEM images and other data that were collected from these studies, on other internal documents concluding the same thing—in addition to his education, experience, and the scientific literature. There is ample support for Dr. Guelcher's opinions in this case, and Ethicon has not provided a basis for excluding them.²¹

Finally, any argument that the FDA's historical classification of Prolene is relevant to determining what Dr. Guelcher can rely upon at trial is without merit and should be disregarded. This Court has previously allowed Dr. Guelcher to rely on these internal Ethicon documents without needing to admit evidence relating to the FDA or its processes, and it has nothing to do

¹⁸ Ex A, Dr. Guelcher's Report, *see also* Ex. B, Dr. Guelcher's reliance materials.

¹⁹ Def's Brief at 11.

²⁰ Ex. D, ETH.MESH.05453719.

²¹ Ex A, Dr. Guelcher's Expert Report at 13-14.

with the defects inherent to the device at issue.²² Moreover, allowing this FDA evidence is entirely unnecessary and will only create undue confusion and waste judicial time and resources at trial.

3. Dr. Guelcher's reliance materials support his opinions about the foreign body response causing mesh complications.

Dr. Guelcher's reliance materials include several peer-reviewed publications, as well as many of Ethicon's internal documents, that link the foreign body response and/or polypropylene oxidation and degradation to mesh complications. His opinion that mesh oxidation and degradation can cause complications are based on his experience in implantable biomaterials those source materials. He is not, however, a medical doctor and he has not offered any case-specific opinions in this Wave of cases. His opinion is general in nature and would not require a differential diagnosis as Ethicon argues.

Additionally, Ethicon's Motion mischaracterizes the recent peer-reviewed paper that Dr. Guelcher authored with Dr. Iakovlev and Dr. Bendavid. As the title suggests, *Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients* is a paper describing the use of a common microscopic technique that pathologists can use to find evidence of degraded polypropylene on explanted meshes. It is not focused on understanding injuries like chronic mesh-pain.²³ This paper is a teaching publication, designed to help pathologists and other researchers look for mesh degradation in their labs around the world. The scientific literature and Ethicon's internal documents support the idea that complications arise from oxidation of heavier weight materials—Dr. Guelcher's opinion on this matter is sound and fully supported.

²² See generally, *Huskey*, 29 F. Supp. 3d 691.

²³ See generally, Ex. F, Iakovlev VV, Guelcher SA, Bendavid R. 2015. Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients. J Biomed Mater Res Part B 2015:00B:000–000.

II. DR. GUELCHER WILL NOT BE TESTIFYING ABOUT CORPORATE INTENT

Counsel for Ethicon correctly points out that this Court has previously disallowed experts to testify regarding a corporation's knowledge or state of mind. Dr. Guelcher only intends to testify as to Ethicon corporate documents at trial for the purpose of explaining the basis for his opinions, in accordance with this Court's previous ruling on this issue.²⁴

CONCLUSION

Ethicon's Motion argues nothing new. Instead, it seeks to undermine Dr. Guelcher's well-vetted opinions based only on the fact that he exercised restraint and did not rely on the results of an unfinished study. The scientific literature supports all of his opinions and the arguments made that challenge their reliability have no merit. For the reasons above, Defendant's Motion to Exclude the Testimony and Opinions of Dr. Scott Guelcher, Ph.D. should be denied in its entirety.

This 9th Day of May, 2016

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²⁴ *Huskey*, 29 F. Supp. 3d 691.

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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